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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,992	06/27/2003	Laith Haddad	H132 1010.1	6418

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EXAMINER

WITZ, JEAN C

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 12/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/608,992

Applicant(s)

HADDAD, LAITH

Examiner

Jean C. Witz

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-5 and 7-18 is/are allowed.
- 6) ☒ Claim(s) 6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_.

**DETAILED ACTION**

***Claim Rejections - 35 USC § 101***

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 6 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 6 recites a synthetic urine composition. Insofar as natural urine is a solution containing a variety of chemicals in various concentrations dependent upon the physiology of the individual from whom it is obtained, synthetic urine is prepared to mimic natural urine to render it indistinguishable from natural urine. As recited, claim 6 recites a composition encompasses a product of nature, urine, and the term "synthetic" recites merely an intended use of the composition and fails to confer any distinguishing structural differences between the claimed composition and a product of nature.

***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claim 6 is rejected under 35 U.S.C. 102(b) as being anticipated by any of U.S.

Patent 5,100,807 to Adamczyk et al., U.S. Patent 4,825,851 to Cocks et al., U.S. Patent 4,714,564 to Lynch et al., or U.S. Patent 4,024,256 to Griffith et al.

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4. The claim recites a synthetic urine composition containing urea and creatinine and having a pH between about 5.0 and about 8.0 and a specific gravity of between about 1.010 and 1.020.

All of the references disclose synthetic urine compositions. See U.S. Patent 4,024,256 to Griffith et al. at col. 11, lines 5-20, U.S. Patent 4,714,564 to Lynch et al. at col. 5, lines 5-30, U.S. Patent 4,825,851 to Cocks et al. at col. 4, lines 40-50, and U.S. Patent 5,100,807 to Adamczyk et al. at col. 6, lines 10-20. The specific gravity of any solution is dependent upon the concentrations of dissolved substances; similarly the pH of a solution is dependent upon the concentrations of hydrogen ions. U.S. Patent 4,590,800 to Shimoda discloses that normal human urine has a specific gravity from 1.005 to 1.035. Since the cited references teach compositions for use as artificial urines with defined solutes, the pH and specific gravities of the solutions are deemed to be inherent in the disclosure of the compositions of the synthetic urines of the prior art and to therefore meet the limitations of the claimed synthetic urine. In fact, U.S. Patent 5,100,807 to Adamczyk et al. explicitly discloses the pH of the synthetic urine to be within the claimed range.

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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6. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over any of U.S. Patent 5,100,807 to Adamczyk et al., U.S. Patent 4,825,851 to Cocks et al., U.S. Patent 4,714,564 to Lynch et al., or U.S. Patent 4,024,256 to Griffith et al. in view of U.S. Patent 4,590,800 to Shimoda.

The disclosures of the primary references are discusses supra. U.S. Patent 4,590,800 to Shimoda discloses artificial urine compositions containing urea can be formulated to have a variety of specific gravities dependent upon the amount of water used as the solvent. The patent also teaches that the normal human urine has a specific gravity from 1.005 to 1.035. It would have been obvious to one of ordinary skill in the art at the time the invention was made to formulate synthetic urine compositions containing creatinine and urea and having a pH between about 5.0 and about 8.0 and a specific gravity of between about 1.010 and about 1.020 because each of these components and characteristics are known to be present in various combinations in synthetic urines and that these compounds and characteristics are also present in normal urine. One of ordinary skill in the art would be motivated to prepare a synthetic urine that is similar in its components and characteristics as normal human urine in order to assure the user of the synthetic urine for calibration of diagnostic machines and for evaluation of medical compositions that the results are most comparable to that which would result from the use of natural urine. One of ordinary skill would have had a reasonable expectation of success since the prior art shows that the claim limitations are known to be a function of the amounts of the components of natural urine.

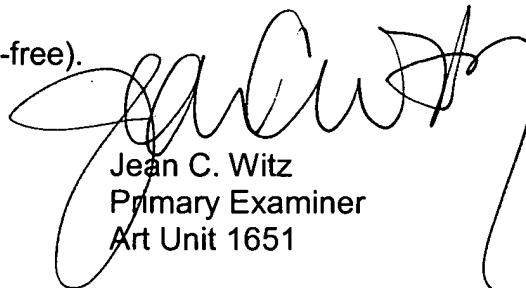
***Allowable Subject Matter***

7. Claims 1-5 and 7-18 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jean C. Witz whose telephone number is (571) 272-0927. The examiner can normally be reached on 6:30 a.m. to 4:00 p.m. M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jean C. Witz  
Primary Examiner  
Art Unit 1651